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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,588

04/04/2006

Keiichi Hirano

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,588	<b>Applicant(s)</b> HIRANO, KEIICHI	
	<b>Examiner</b> MELISSA PERREIRA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, claims 1-5 and 11 in the reply filed on 9/17/09 is acknowledged. The traversal is on the ground(s) that the search of group I would necessarily encompass examination and searching of the subject matter of claims 6-10 and 12. Applicant asserts that the Examiner has not shown that it would be a burden to examine all of the species. This is not found persuasive because the apparatus may contain resins having different chemical formulas and thus the process can be practiced via another materially different apparatus. The resin material species have different chemical formulas and thus would require a separate search. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 6-10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group II and species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/17/09.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (US 5,932,178) in view of Osaki et al. (JP 08-325169) and in further view of Hyodo et al. (US 6,827,838B2).

5. Yamazaki et al. (US 5,932,178) discloses a process for labeling FDG with  $^{18}\text{F}^-$  via a FDG synthesizer comprising a labeling reaction resin column, such as a polymer-supported phase-transfer catalyst resin (i.e. polystyrene resin) having a fixed phosphonium salt. The  $^{18}\text{O}$  (water),  $^{18}\text{F}^-$  is passed through the column to trap  $^{18}\text{F}^-$  as the column was heated within a range of from 80 to 100°C. Acetonitrile is passed through the column containing  $^{18}\text{F}^-$  to dry the labeling reaction resin. Helium gas was passed through the labeling reaction resin to sufficiently dry the column. Then, a triflate solution (i.e. 1,3,4,6-tetra-O-acetyl-2-O-trifluoromethanesulfonyl- $\beta$ -D-mannopyranose) is passed through the dried labeling reaction resin column to cause a displacement reaction (column 7, lines 30-63; column 2, lines 31-38; example 4). The FDG synthesizer comprises a flow rate control means. Yamazaki et al. does not disclose the step of passing carbon dioxide through the column or the anion-exchange resin of the instant claims 4 and 11.

6. Osaki et al. (JP 08-325169) discloses the process of producing a  $^{18}\text{F}$ -labeled organic compound in high yield using a phosphonium resin where the ring P is a crosslinked alkylstyrene halide-styrene copolymer carrier; Y is an alkyl; and Z is a counter ion, not excluding  $\text{HCO}_3^-$  or  $\text{CO}_3$  (below). The process involves containing the  $^{18}\text{F}$ -containing water and treating the resin with a solution containing a substrate of the formula XR (where X is a leaving group).

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7.

8. Hyodo et al. (US 6,827,838B2) discloses the method of separating and recovering  $^{18}\text{F}^-$  from  $^{18}\text{O}$  water at high purity and efficiency (abstract) as  $^{18}\text{O}$  water is expensive, and since a few grams of it is required for a single irradiation and generation of  $^{18}\text{F}^-$ . A conventional  $^{18}\text{F}^-$  recovery method is based on the use of an ion exchange resin where  $^{18}\text{F}^-$  is separated from  $^{18}\text{O}$  water by ion exchange, and then the  $^{18}\text{F}^-$  is recovered from the ion exchange resin by using, e.g., carbon dioxide (column 1, lines 29-49).

9. At the time of the invention it would have been obvious to one skilled in the art to substitute/utilize the phosphonium-crosslinked alkylstyrene halide-styrene copolymer resin of Osaki et al. for the polymer-supported phase-transfer catalyst resin (i.e. polystyrene resin) having a fixed phosphonium salt of Yamazaki et al. as both disclosures are drawn to the process for  $^{18}\text{F}$ -labeling organic compounds. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect.

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize carbon dioxide to completely and efficiently separate and recover  $^{18}\text{F}^-$  from  $^{18}\text{O}$  water and allow for the reuse of  $^{18}\text{O}$  water as it is costly. The reference of Yamazaki et al. teaches of a FDG synthesizer comprising a flow rate control means and

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thus the rate of the flow of the synthesis constituents, such as carbon dioxide can be controlled and it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618